UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, Defendants.	No. 25-CV-00849-EP-JRA

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' ORDER TO SHOW CAUSE FOR PRELIMINARY INJUNCTIVE RELIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and Novadoz Pharmaceuticals LLC ("Novadoz") (collectively, "MSN"), respectfully submit this memorandum of law in opposition to Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation's (collectively, "Novartis") Motion for Preliminary Injunctive Relief.

PRELIMINARY STATEMENT

For six years, Novartis has waged a multi-pronged, scorched-earth litigation campaign to prevent MSN from coming to market with an FDA-approved generic version of Novartis's Entresto heart medication. This strategy includes multiple lawsuits against MSN and even the U.S. Food and Drug Administration ("FDA"), all seeking injunctive relief before various district and appellate courts in a stop-at-nothing effort to stretch Novartis's monopoly rights under expired or invalid patents.

Novartis now reaches into its playbook for yet another litigation gambit: an eleventh-hour "trade dress" claim requesting an "emergency" TRO and preliminary injunction purporting to raise public health concerns. But Novartis fails to tell this Court that the FDA and D.C. district court *already considered and rejected one of the core grounds on which Novartis seeks relief*—the alleged safety concern arising from the dosing instructions on MSN's label. Simply put, after reviewing MSN's extensive ANDA filings, FDA found MSN's drug to be safe and effective.

Equally troubling is the strategic timing of Novartis's motion. Contrary to its

representations to this Court,[1] *Novartis has been aware of the appearance of MSN's pills at issue for over four years and even had one of its experts test the physical pills three years ago.* Yet Novartis did absolutely nothing to raise its trade dress concern with MSN or seek any judicial relief. Similarly, Novartis has been aware *since 2018* that Defendant Novadoz adopted, extensively used, and secured a federal trademark registration for the brand name "NOVADOZ" for its generic drug business, but once again Novartis did nothing about it. Under hornbook Third Circuit law, Novartis's delay, standing alone, mandates denial of a preliminary injunction.

Though the absence of irreparable harm is dispositive, Novartis also has failed to meet its high burden of showing any likelihood of success on the merits of its trade dress claim. *First*, under controlling Third Circuit law, color-coding of pharmaceutical pills like those at issue here is functional, and thus categorically ineligible for exclusive trade dress protection, because it conveys critical dosing information to patients. *Second*, Novartis cannot show that the commonly used generic shapes, sizes and colors of its individual tablets (as opposed to the "Entresto" name) have secondary meaning. It speaks volumes that Novartis, with its endless resources, has failed to introduce a consumer survey or indeed a single affidavit from

[1] Novartis's Global Head of Legal Brand Protection states in a sworn declaration that "Novartis bec[a]me aware that the appearance of" MSN's generic Entresto "could resemble that of ENTRESTO®" only on August 6, 2024. *See* Decl. of David Lossignol ("Lossignol Decl.") ¶ 10.

a patient claiming that the so-called Entresto trade dresses are source identifiers. And finally, Novartis has not shown any plausible likelihood of confusion. MSN's products and labels have their own distinctive markings and do not bear the well-known brand name Entresto.

Novartis's trademark claim based on MSN's use of the trademark NOVADOZ fares no better. MSN has publicly and extensively used that mark for close to seven years without any marketplace confusion with Novartis, which is not surprising as the marks have wholly different meanings, and countless third parties use the common prefix "nova." Making confusion even less likely, Novartis readily admits that its products are closely associated with the well-known Entresto name which appears nowhere on MSN's product. And Novartis's attempt to salvage its infringement claim based on alleged similarity with past uses of "Sandoz" is absurd. Novartis sold Sandoz in October, 2023 and therefore assigned away any goodwill associated with that name.

The Court should make no mistake: Novartis's current motion is a transparent attempt to inflict irreparable harm on a generic competitor as part of a larger litigation strategy. If an injunction were granted pending trial, MSN would likely forfeit years of research and developmental efforts, lose the critical "first mover advantage" while other companies launch their generic versions of Entresto, and suffer irreparable reputational damage among its suppliers and business partners.

None of the relevant factors for an injunction support such a result in this case. The Court should deny Novartis's motion in full.

BACKGROUND

I. MSN's Generic Medication Business and Longstanding Use of the NOVADOZ Mark.

Established in 2003 in Hyderabad, India, MSN is a fast-growing pharmaceutical company specialized in developing, manufacturing, and distributing high-quality generic medications. Decl. of Bharat Reddy Chintapally ("Chintapally Decl.") ¶ 2. Generic medications perform identically to their branded counterparts but cost only a fraction of their price.[2] MSN and other generic manufacturers thus play a pivotal role in securing public access to life-saving treatments. Chintapally Decl. ¶ 27; *see* Decl. of Ravikumar Nithiyanandam ("Nithiyanandam Decl.") ¶ 17.

Novadoz was established in 2018 as the United States marketing and sales arm for MSN's products. Decl. of Venkatesh Srinavasan ("Srinavasan Decl.") ¶¶ 1, 5. The NOVADOZ name was formed by combining "Nova," meaning a new bright star, and "doz," which sounds identical to the word "dose." Chintapally Decl. ¶ 5. The name thus conveys an impression of newness and brightness while referencing the company's pharmaceutical products. *Id.* Reinforcing that meaning, Novadoz consistently uses the tagline "Value in every dose" in its marketing materials. *Id.* In

[2] Decl. of Martin Shimer ("Shimer Decl") ¶¶ 13–14; Decl. of Dr. Hossein Ardehali ("Ardehali Decl.") ¶¶ 38–39; Decl. of Todd Clark ("Clark Decl.") ¶¶ 16–17, 19–24.

2020, the U.S. Patent and Trademark Office ("PTO") granted Novadoz a registration for the word-and-design mark "NOVADOZ VALUE IN EVERY DOSE," based on a first use in commerce in January 2018. Chintapally Decl. ¶ 8 & Ex. 1.

In August 2018, MSN announced the launch of its first three products under the NOVADOZ trademark, all of which were generic equivalents of popular branded drugs. Srinavasan Decl. ¶ 7. Since then, MSN has maintained a steady pipeline of new products, launching an additional ten product families in 2019. *Id.* ¶ 8. Today, MSN sells over 60 different product families in the United States under the mark NOVADOZ, including two heart disease medications and one generic equivalent of a Novartis product, which MSN launched in 2021.[3] *Id.* ¶¶ 9–10, 13.

II. U.S. Policy and Regulations Concerning Generic Drugs.

"[T]he enactment in 1984 of the Hatch-Waxman amendments to the Food, Drug and Cosmetic Act . . . established a federal policy favoring the marketing of" generic alternatives to higher-priced branded drugs. *Shire US Inc. v. Barr Lab'ys, Inc.*, 329 F.3d 351 n.14 (3d Cir. 2003). Generic substitution drastically decreases costs for consumers, insurance companies, and government programs such as Medicaid and Medicare and is thus a crucial element in the fight against rising health

[3] No MSN product has ever been commercialized in the U.S. under "MSN" branding. Instead, with a few exceptions sold through third-party distribution partners, since 2018, all of MSN's products have been distributed in the U.S. by Novadoz and under the NOVADOZ trademark. Srinavasan Decl. ¶ 14.

care costs. Chintapally Decl. ¶ 27; Clark Decl. ¶¶ 30–32; Shimer Decl. ¶¶ 17–23.

As part of that policy, FDA allows pharmaceutical companies to apply for FDA approval of generic drugs using an abbreviated new drug application ("ANDA"). Clark Decl. ¶¶ 25–27. To receive ANDA approval, a generic drug must be proven to be functionally identical to the reference branded drug: it must be in the same dosage form (e.g., tablet, capsule, or liquid), and it must be "bioequivalent," which means that it delivers the same dose of the active ingredient as the branded drug in the same amount of time. *Id.*; Nithiyanandam Decl. ¶ 4.

As explained in the declaration of Martin Shimer, who spent twenty-two years with FDA and was the Deputy Director of the FDA's Office of Generic Drugs, Division of Legal and Regulatory Support, the published guidance from FDA recommends that generics be similar in size, shape, and appearance to the reference drug in order to enhance patient familiarity and minimize any confusion in the use of the generic alternative. Shimer Decl. ¶¶ 27–47 ("ANDAs which follow the physical attributes, including color, of a branded RLD are routinely reviewed and approved by FDA and are available in the marketplace."). It is therefore standard industry practice for generic drugs to visually reference the appearance of their branded equivalents. Nithiyanandam Decl. ¶ 6. Indeed, as shown in the expert report of Todd Clark, a statistical analysis comparing physical aspects of commonly used generic drugs with their branded counterparts shows a high degree of similarity

in shape, size, and color. Clark Decl. ¶ 102; *see generally id.* ¶¶ 82–103.

III. MSN's Development of Its Generic Version of Entresto.

MSN began developing a generic equivalent to Novartis's Entresto product around 2017. Nithiyanandam Decl. ¶ 3. MSN invested over $12 million dollars in research and development costs with the goal of becoming the first entrant in the market for generic Entresto products. Chintapally Decl. ¶ 30. Being the "first mover" in the market for a new generic confers key advantages, including the ability to secure long-term contracts with "right of first refusal" terms from key customers. *Id.* ¶ 31; Shimer Decl. ¶ 51.

MSN submitted an ANDA for FDA approval of its generic Entresto product on July 7, 2019. Nithiyanandam Decl. ¶ 3. As required, the ANDA contained detailed information about MSN's tablets' proposed appearance. The appearance of MSN's tablets was driven largely by functional and regulatory considerations. *Id.* ¶¶ 10, 12, 13, 15, 18. MSN used a generic ovaloid shape that is known to be easy to swallow. *Id.* ¶¶ 12, 18. It used colors that are ubiquitous in the pharmaceutical industry (purple, yellow, and pink) and are therefore readily available to procure and source. *Id.* ¶ 11; *see also* Decl. of Jacquellena T. Carrero ("Carrero Decl.") Ex. 1 (summarizing pills with similar features); Clark Decl. ¶¶ 51–53, 82–99. Further, because Entresto tablets are color-coded to indicate dosage, MSN chose colors that reference Entresto's color-coding so that patients taking MSN's generic equivalent

could rely on familiar visual cues to identify what drug and which dose they are taking. Nithiyanandam Decl. ¶ 18.[4]

But MSN also took steps to differentiate its pills from Entresto. Nithiyanandam Decl. ¶ 15. For example, Entresto pills feature "NVR" markings on one side whereas MSN's pills feature "M" markings; the markings on the reverse sides of the pills are different as well. *Id.* MSN also used a different sizing scheme: all three of MSN's pills are different sizes whereas Entresto's tablets only come in two sizes. *Id.* And the colors MSN uses are noticeably darker than Entresto's. *Id.*

Novartis's representation that it did not learn about the MSN pills' appearance until August 2024, *see* Pls.' Mem. of Law in Supp. Prelim. Inj. Mot. ("Br.") at 11 n.11, ECF 4-1, is simply false. Not only did MSN produce images of the pills to Novartis in June 2020 in the patent litigation discussed below, Decl. of Richard Juang ("Juang Decl.") ¶ 6, in January 2021 MSN sent Novartis *physical samples* of the pills which Novartis *tested*, *id.* ¶ 9.

IV. Novartis's Failed Lawsuits Against FDA

Since April 2019, Novartis has filed numerous "citizen petitions" with FDA

[4] Indeed, so far as can be determined from publicly available information, every other ANDA applicant for a generic Entresto product has made similar decisions regarding their pills' appearance. *Id.* ¶ 18 & Ex. 1. They also color-code their pills according to dosage; also use a similar light purple, pale yellow, and light pink color scheme, and also use an ovaloid shape. Nithiyanandam Decl. ¶ 18 & Ex. 1; *see also* Carrero Decl. Ex. 2 (summarizing other medications that color code doses).

seeking to dissuade it from approving MSN's ANDA for generic Entresto. Chintapally Decl. ¶¶ 13, 15–16. Notably, in one of these petitions, filed in September 2022, Novartis raised the very same argument Novartis asserts in this case: that MSN's proposed label and prescribing information creates a health risk by omitting modified dosing instructions for a certain category of patients. *Id.* FDA denied that petition on July 24, 2024, and approved MSN's ANDA the same day. *Id.*

Just six days later, on July 30, 2024, Novartis filed a lawsuit challenging FDA's approval decision and repeating the labeling argument from its citizen petition. *Id.* ¶ 18. The court, however, rejected the labeling argument (and Novartis's other arguments). *Novartis Pharm. Corp. v. Becerra*, 2024 WL 4492072, at *11 (D.D.C. Oct. 15, 2024). Notably, the court held that FDA had "provided a reasoned scientific basis for its conclusion that [the labeling omission] will not render MSN's generic drug less 'safe or effective.'" *Id.* at *9. The court emphasized that FDA had evaluated "the clinical significance of [Novartis's] study, prevailing medical guidance, and prescriber best practices," *id.* at *10, and that it had "thoroughly explained its rationale for approving MSN's generic label without the dosing regimen in a 45-page response to Novartis's Labeling Petition," *id.* at *9.

Since FDA's approval of MSN's ANDA, Novartis has succeeded in continuing to block the release of MSN's generic drug by obtaining a patchwork of temporary stays from the appellate courts in its patent and regulatory litigations.

Chintapally Decl. ¶¶ 17–20. Currently, the Federal Circuit has enjoined MSN from launching its product pending issuance of its mandate. *Id.* ¶ 20. Faced with the prospect of that injunction expiring, Novartis has turned to yet another court and yet another legal theory, filing the instant litigation here.

LEGAL STANDARD

Preliminary injunctive relief is an "extraordinary remedy, which should be granted only in limited circumstances." *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014). To obtain a preliminary injunction, the moving party bears the burden of establishing that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in its favor, and (4) the public interest favors such relief. *Id.* That burden is heavy: the movant must make a "clear showing" that it is entitled to injunctive relief. *Holland v. Rosen*, 895 F.3d 272, 285–86 (3d Cir. 2018). The movant's failure to establish any element in its favor is fatal and "renders a preliminary injunction inappropriate." *NutraSweet Co. v. Vit-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999).

ARGUMENT

I. NOVARTIS IS HIGHLY UNLIKELY TO SUCCEED ON THE MERITS OF ITS TRADE DRESS CLAIM.

Novartis cannot show a likelihood of success on its trade dress claim. A plaintiff must prove three elements to establish trade dress infringement based on a

product configuration: "(1) the allegedly infringing product design is nonfunctional; (2) the product design . . . has acquired secondary meaning; and (3) consumers are likely to confuse the source of the plaintiff's product with that of the defendant's product." *Fair Wind Sailing, Inc. v. Dempster*, 764 F.3d 303, 309 (3d Cir. 2014). Novartis fails at each step.

A. The Asserted Trade Dress Is Functional.

As the party asserting trade dress protection in unregistered product features, like the shape, size and color of tablets, Novartis bears the burden of proving the asserted protected features are not functional. 15 U.S.C. § 1125(a)(3).

A feature need not be "essential" to a product to be functional—it just needs to give the product "an edge in usefulness." *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, 986 F.3d 250, 255–57 (3d Cir. 2021), *as amended* (Mar. 10, 2021). Thus, if the "exclusive use of [the feature] would put competitors at a significant non-reputation-related disadvantage," it cannot function as a trademark. *Id.* at 257 (internal quotations omitted).

1. The "Trio Trade Dress" Indicates Dosage Information.

Novartis has no protectable rights in the functional color-coding and pill size combination that communicates Entresto's dosage information to consumers—the so-called "Trio Trade Dress." Br. at 6.

Under controlling Third Circuit precedent—which Novartis conspicuously

fails to bring to the Court's attention—the color-coding of a drug that conveys dosage information is functional and non-protectable. *Shire*, 329 F.3d at 349–51. In *Shire*, a case nearly identical to this one, the manufacturer of Adderall accused the manufacturer of a generic equivalent of trade dress infringement based on its use of the same color scheme and sizes for its suite of pills. *Id.* at 349–51. But the generic drug used size and color to indicate dosage—as did its branded counterpart. *Id.* The Third Circuit affirmed the district court's denial of a preliminary injunction, finding that the color-coding scheme was functional because it allowed patients to quickly and accurately identify the correct dosage. *Id.* at 354. The defendant's use of a similar shape and color-coding as the branded counterpart enhanced patient safety and compliance with the prescribed dosing regimen. *Id.* at 355.[5]

Likewise, the Supreme Court, has recognized that "competitors might be free to copy the color of a medical pill where the color serves to identify the kind of medicine (*e.g.*, a type of blood medicine) in addition to its source." *Qualitex Co. v.*

[5] *Shire*'s holding was broad, as it relied on decisions involving non-ADHD medication. *See id.* at 357–58. Indeed, changing pill colors increases patient non-adherence (by as much as 66 percent) for a variety of medications. *See* Clark Decl. ¶ 53 (treatment for seizures and myocardial infarction). In any event, chronic heart failure patients are especially likely to heavily rely on visual cues to identify their pills because they are likely to suffer from comorbidities and take multiple medications. Shimer Decl. ¶ 38. Novartis's own experts acknowledge as much. *See* Decl. of Mark Robbins ("Robbins Decl.") ¶ 14; Nayeri Decl. ¶¶ 49, 60.

Jacobson Prods. Co., 514 U.S. 159 (1995).[6] And a Supreme Court concurring opinion characterized shapes and colors of generic drugs as "functional," explaining that "color or shape may be a convenient shorthand code by which to identify the drug and its milligram dosage so that mistakes can be avoided in the interests of pharmaceutical precaution and patient safety." *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 862 n. 3 (1962) (White, J., concurring) ("[C]onstancy of color and shape may be as psychologically reassuring and therefore as medically beneficial as the drug itself.").

Here, as in *Shire*, the colors and sizes of Entresto pills communicate crucial functional information to patients—namely, what drug each pill is and what dose it contains. *See* Nithiyanandam Decl. ¶ 10; Shimer Decl. ¶¶ 27–47; Clark Decl. ¶¶ 47–59; *Shire*, 329 F.3d at 355 (pill colors are functional where they are "directly linked to the drug's efficacy" (quotation marks omitted)). Indeed, Novartis's own marketing materials directly link the different pill colors to different dosages which is strong evidence of functionality.[7] *Am. Greetings Corp. v. Dan-Dee Imports, Inc.*,

[6] Other circuits agree that "color coding [which] helps users identify useful product characteristics" is functional and ineligible for trade dress protection. *Sulzer Mixpac AG v. A&N Trading Co.*, 988 F.3d 174, 182 (2d Cir. 2021) (color of dental tool tips indicated diameter); *see also Al-Site Corp. v. VSI Intern., Inc.*, 174 F.3d 1308, 1328–29 (Fed. Cir. 1999) (color of eyeglass display racks indicated glasses' strength).

[7] Carrero Decl. Ex. 13; Decl. of Megan Bannigan ("Bannigan Decl.") Exs. 42–43, 46–47.

807 F.2d 1136, 1143 (3d Cir. 1986).[8]

Novartis's argument that MSN "could have developed its own distinct design," Br. at 19, misunderstands the functionality doctrine in this context. First, a product design can be functional "even when there are alternatives." *Ezaki Glico*, 986 F.3d at 260. Novartis's cherry-picked examples of other pills in different shapes and colors do not make the colors and sizes of Novartis's pills less useful to patients. *Id.*

Second, there simply are *no* adequate alternative designs here, as proven by the fact that other aspiring manufacturers of generic Entresto for which public information is available appears to have chosen similar pill shapes, sizes, and colors to MSN's. Nithiyanandam Decl. ¶ 18.[9] As the Third Circuit noted in *Shire*, "similarity in tablet appearance enhances patient safety by promoting psychological acceptance" of generic drugs. 329 F.3d at 358. And as reported in the expert

[8] Even Novartis's own experts acknowledge that patients—particularly those with chronic conditions like those treated with Entresto—"rely on pill appearance to help identify which medication to take." Robbins Decl. ¶¶ 13–15; Nayeri Decl. ¶ 60 ("many [patients] simply recognize the color and the shape of their drugs"). These admissions from Novartis's own experts weigh heavily against any claim of exclusive rights in these features.

[9] The cases Novartis cites to challenge the functionality of pill colors are all from the early 1980s—before the passing of the Hatch-Waxman Amendments, which drastically reshaped the landscape for generic drugs—and thus predate *Shire* by two decades. *Shire* addresses these older cases directly, explaining that they have been rendered stale by both (a) the passing of the Hatch-Waxman Amendments and (b) more recent Supreme Court "trade dress decisions which caution against the over-extension of trade dress protection." *Shire*, 329 F.3d at 355 & n.14, 358.

declaration of Todd Clark, changing a pill's appearance can lead to dramatic reduction in patient adherence to their drug regimens. Clark Decl. ¶ 53. For these reasons (and others), FDA itself recommends that "efforts should be made to develop [generic] tablets and capsules that are of a similar size and shape to the" branded equivalent. Nithiyandam Decl. ¶ 8; Shimer Decl. ¶¶ 27–47.

2. The Trade Dress of Individual Entresto Pills Is Also Functional.

The colors, shapes, and sizes of individual Entresto pills are "not arbitrary or ornamental flourishes that serve only to identify [Novartis] as the source" of Entresto, but rather convey significant functional benefits in efficacy and patient adherence. *Ezaki Glico*, 986 F.3d at 259.

Color. For chronic heart failure patients who use multiple medications, pill color serves the functional purpose of helping them identify the correct medication to take. Nithiyanandam Decl. ¶ 10; Carrero Decl Ex. 2; Clark Decl. ¶¶ 49–51.

Shape. "[A] product's . . . shape[] is often useful and thus functional." *Ezaki Glico*, 986 F.3d at 258. The ovaloid shapes that Novartis and MSN (and other generic manufacturers) chose for their tablets are functional because they make pills easier to (1) manufacture and (2) swallow. Nithiyandam Decl. ¶ 12; Shimer Decl. ¶¶ 31–

32.[10] The availability of thousands of ovaloid pills on the market confirms the usefulness of that shape. Nithiyandam Decl. ¶ 12; Carrero Decl. Ex. 1. Novartis's own expert acknowledges that ovals and capsules are common, functional pill shapes rather than purely ornamental source signifiers. Robbins Decl. ¶ 12.

Size. Similarly, the sizes of Entresto tablets reflect functional considerations other than source identification. Nithiyandam Decl. ¶ 17. There are only so many sizes available to manufacturers who want their pills to be easy for patients to swallow. *Id.* And Novartis's decision to make its highest-dose Entresto pill bigger than the medium and low doses reflects a practical choice driven by the larger amount of the active ingredient contained in the pill and the desire to help patients and HCPs easily identify their required dose. Shimer Decl. ¶¶ 30–31 (discussing the FDA's recommendation that efforts should be made to develop tablets and capsules that are of a *similar size and shape*).

B. The Asserted Trade Dresses Are Generic.

"A product design that is widely and commonly used by several producers may be classified as 'generic' and thus cannot serve a trademark role of identifying only one source." 2 McCarthy on Trademarks and Unfair Competition § 12:36.50 (5th ed.); *see also id.* at § 8:6.50 (5th ed.). Generic trade dress is categorically

[10] In *Ezaki Glico*, the Third Circuit affirmed a finding that the design of Pocky's partly-chocolate-coated stick snacks was functional, in part because it facilitated consumption. 986 F.3d at 259–60.

ineligible for trademark protection, *see A.J. Canfield Co. v. Honickman*, 808 F.2d 291, 297 (3d Cir. 1986); *Eagle Snacks, Inc. v. Nabisco Brands, Inc.*, 625 F. Supp. 571, 580 (D.N.J. 1985).

Extensive third-party use supports a finding that an asserted trade dress is generic. *McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC*, 511 F.3d 350, 353 (3d Cir. 2007) (noting that there were other yellow packages in sugar aisle other than plaintiff's product and therefore the court could not conclude that consumers associate use of yellow with plaintiff); *Mana Prods., Inc. v. Columbia Cosmetics Mfg., Inc.*, 65 F.3d 1063, 1069–70 (2d Cir. 1995) (makeup compacts' size and shape was common and thus generic).

Here, there are countless pills with the same ovaloid shape as Entresto. Nithiyandam Decl. ¶ 12; Clark Decl. ¶¶ 83–84; Carrero Decl. Ex. 1. Indeed, Novartis' own expert cites Entresto's basic ovaloid shape as one of twelve "common tablet shapes." Robbins Decl. ¶ 12. Likewise, there are many off-white, yellow, and pink pills on the market, including heart medications. Carrero Decl. Ex. 1. Such extensive use of this ovaloid common pill shape and common colors in the health care industry market strongly negates any showing that Novartis's trade dress is protectable.[11]

[11] Any argument by Novartis that the Court should disregard third-party uses outside the narrow market for chronic heart failure drugs cannot be squared with actual

C. The Asserted Trade Dresses Lack Secondary Meaning.

Assuming they were not categorically ineligible for protection, the Entresto trade dresses are unprotectable because they lack secondary meaning and therefore are not entitled to protection as a mark. *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 216 (2000) ("We hold that . . . a product's design is distinctive, and therefore protectable, only upon a showing of secondary meaning.").

Secondary meaning exists only when "in the minds of the public, the primary significance of a [mark] is to identify the source of the product rather than the product itself." *Id.* at 211 (quoting *Inwood Lab'ys, Inc.*, 456 U.S. at 851 n. 11). The factors relevant to this determination include the length and exclusivity of use of the alleged trade dress, direct customer surveys or testimony regarding the recognition of the trade dress, sales, the nature and extent of advertising of the trade dress, and evidence of copying. *Zany Toys, LLC v. Pearl Enterprises, LLC*, 2014 WL 2168415, at *7 (D.N.J. May 23, 2014) (numbering omitted). A review of these factors shows that Novartis has not shown a likelihood of success in establishing secondary meaning in any of its claimed trade dress.

---

market conditions. As Novartis's own expert acknowledges, "patients with chronic conditions are more likely to take multiple medications relative to other patients." Robbins Decl. at 6; *see also* Shimer Decl. ¶ 48. Thus, over the past decade, Entresto patients have been exposed to a wide array of drugs that share Entresto tablets' common physical characteristics. *See* Carrero Decl. Ex. 1; Clark Decl. at V.A.

1. Novartis Does Not Have Exclusive Use of the Asserted Trade Dresses.

As explained above, the Entresto trade dresses consist of ubiquitous pill sizes, shapes, and colors. *See supra* at 11–18. These features' "primary significance" in consumers' minds cannot possibly be to identify Novartis when numerous third parties use those sizes, shapes, and colors as well. This factor alone negates any possible showing that the *primary significance* of oval-shaped violet, yellow or pink tablets, alone or in combination, is to designate the source of Entresto in the market. *See Truinject Corp v. Galderma S.A.*, 694 F. Supp. 3d 491, 507 (D. Del. 2023) (citing *Com. Nat. Ins. Servs., Inc. v. Com. Ins. Agency, Inc.*, 214 F.3d 432, 440–41 (3d Cir. 2000)) ("[T]he presence of similar products . . . militates against a finding of secondary meaning as consumers would not associate [the trade dress] with any individual company.").

2. There Is No Direct Evidence That Consumers Associate the Claimed Trade Dresses with Novartis.

Notwithstanding that Novartis has sold Entresto for many years and has abundant financial resources, Novartis has failed to offer a shred of direct evidence that any consumer associates the Entresto trade dresses with Novartis. It has not done a secondary meaning survey. Nor has it presented the Court with a single declaration from any of the millions of Entresto patients. This omission weighs strongly against a likelihood of success as "[c]ourts place particular weight in customer surveys and

testimony because . . . they are the only direct evidence of secondary meaning." *Richardson v. Cascade Skating Rink*, 2024 WL 3841942, at *8 (D.N.J. Aug. 16, 2024) (lack of survey weighed against finding of secondary meaning).[12]

3. Novartis Has Engaged in No Relevant Advertising of the Claimed Trade Dress as a Source Identifier

Novartis's attempt to overcome its lack of any direct consumer evidence by citing advertising materials, *see* Br. at 21–22, also misses the mark.

None of Novartis's consumer-facing marketing materials highlight the pills' appearance as a designation of source, *i.e.,* for example by telling consumers to "look for" recognizable colors and shapes. Instead, when Novartis includes images of its Entresto pills in consumer-facing communications, it does so in a functional way, associating each pill with a particular dose of the drug—not to suggest that the pills' appearance indicates source.[13] These incidental, descriptive depictions of the pills do not establish secondary meaning. *See Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1453 (3d Cir. 1994) (finding no secondary meaning after concluding that "[Plaintiff] has not emphasized its alleged trade dress in its

[12] Even Novartis's paid expert does not purport to opine that relevant patients actually have come to associate the alleged trade dress exclusively with Novartis and instead merely speculates about how pill shapes in advertising *could* be perceived as a visual cue for Entresto. *See* Robbins Decl. ¶ 17.

[13] *See* Bannigan Decl. Ex. 42 (featuring pills when describing doses); Bannigan Decl. Ex. 47 (featuring pills on fifth page of brochure in "How To Take Entresto" instruction); *see also* Br. at 8 (stating that Novartis "highlight[s] the ENTRESTO® Trade Dresses when introducing HCPs to the drug's three doses").

advertising, relying instead primarily on small depictions of the entire product"); *Buzz Bee Toys, Inc. v. Swimways Corp.*, 20 F. Supp. 3d 483, 500 (D.N.J. 2014) ("To be probative of secondary meaning, the advertising must direct the consumer to those features claimed as trade dress.").

Indeed, Novartis's marketing strategy stands in stark contrast to that of other drugs which *do* emphasize their appearance as having brand significance. Nithiyanandam Decl. ¶ 14. For example, AstraZeneca advertises its Nexium product as "the purple pill," including through the website purplepill.com.[14] It has obtained three federal trademark registrations covering the color purple, and one covering the phrase THE PURPLE PILL, for gastrointestinal pharmaceuticals. *Id.* Novartis offers no evidence that it has engaged in this sort of marketing to consumers.[15]

D. There Is No Likelihood of Confusion.

Finally, even if Novartis could show its trade dress is nonfunctional and has achieved secondary meaning, which it cannot, Novartis has failed to demonstrate a

[14] *Astrazeneca AB v. Dr. Reddy's Laboratories, Inc.*, 145 F. Supp. 3d 311, 313–14 (D. Del. 2105).

[15] Novartis's argument that secondary meaning can be inferred from the mere fact that MSN's pills are similar in appearance to Entresto is transparently meritless. *See* Br. at 22–23. Even actual "[a]ttempts to copy a product configuration will quite often not be probative: the copier may very well be exploiting a particularly desirable feature, rather than seeking to confuse consumers as to the source of the product." *Duraco Products, Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431 (3d Cir. 1994). The overwhelming evidence of third-party use of Entresto's claimed features, *see supra* at 11–18, and FDA's recommendations to follow the branded drug's appearance, *see supra*, amply explain MSN's pill configuration.

plausible likelihood of confusion between Entresto and MSN's generic product.

To assess likelihood of confusion, courts in the Third Circuit consider the following non-exclusive factors:

> (1) the degree of similarity between the owner's mark and the alleged infringing mark; (2) the strength of the owner's mark; (3) the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase; (4) the length of time the defendant has used the mark without evidence of actual confusion arising; (5) the intent of the defendant in adopting the mark; (6) the evidence of actual confusion; (7) whether the goods, though not competing, are marketed through the same channels of trade and advertised through the same media; (8) the extent to which the targets of the parties' sales efforts are the same; (9) the relationship of the goods in the minds of consumers because of the similarity of function; (10) other factors suggesting that the consuming public might expect the prior owner to manufacture a product in the defendant's market, or that he is likely to expand into that market.

Interpace Corp. v. Lapp, Inc., 721 F.2d 460, 463 (3d Cir. 1983).[16]

Factor 1: The Parties' Trade Dresses Are Dissimilar. MSN's pills visually resemble Entresto only to the extent sufficient to satisfy functional and regulatory requirements, including FDA's preference for generic pills that call to mind their branded counterparts. *See generally* Shimer Decl.; Clark Decl. In other respects, the appearance of MSN's pills clearly distinguishes them as generic products that are not produced by Novartis. Nithiyandam Decl. ¶ 15.

[16] Contrary to Novartis' contention, there is no "lesser" burden of proof for likelihood of confusion in cases involving pharmaceuticals. *See* Br. at 24. Novartis points to no Third Circuit authority supporting that rule, which makes particularly little sense here because the parties' drugs are medically equivalent.

As described above, the markings on the pills are completely different, MSN and Entresto's pills come in different sizes for their highest dose, and the MSN pills have darker coloring. *See supra* at 8.[17]

Novartis's consistent use of its house mark NOVARTIS and of the well-known product mark ENTRESTO further serve to clearly differentiate these products in the marketplace.[18] *See McNeil Nutritionals, LLC*, 511 F.3d at 361 (affirming denial of preliminary injunction when presence of product name on package was sufficient to prevent likelihood of confusion). This factor weighs in MSN's favor.

Factor 2: The Entresto Trade Dress Is Very Weak. The same evidence showing that the Entresto trade dress is functional, generic, and lacking in secondary meaning also supports a finding that it is weak. *See supra*. Thus, this factor also weighs in MSN's favor. *See, e.g.*, *What a Smoke, LLC v. Duracell U.S. Operations, Inc.*, 2024 WL 1327976, at *9 (D.N.J. Mar. 27, 2024) (holding second *Lapp* factor favored defendant where plaintiff's mark was descriptive and widely used by third parties).

---

[17] *Astrazeneca AB v. Dr. Reddy's Laboratories, Inc.*, 145 F. Supp. 3d 311 (D. Del. 2105), which Novartis cites for the proposition that different markings on pills do not prevent confusion, is distinguishable because it involved Nexium, which, as explained above, is aggressively marketed with reference to its registered trademarks covering the color purple. *See id*. at 313.

[18] *See, e.g.*, Miller Decl. ¶¶ 8, 11(advertisements featuring Novartis); Bannigan Decl. Ex. 47 (Entresto webpage and brochure); Bannigan Decl. Ex. 73.

Factor 3: The Relevant Market Is Sophisticated and Exercises Care. Where, as here, the relevant market includes "sophisticated" individuals, confusion is less likely. *Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 187 (3d Cir. 2022) (affirming denial of preliminary injunction where relevant consumers were sophisticated). Here, because the parties' products are prescription medications, the relevant market consists primarily of healthcare professionals, who ordinarily exercise great care and attention when making prescribing decisions and do not decide which drugs to prescribe based on color, shape, or size—much less images of the pills that could be found online. Ardehali Decl. ¶¶ 29–30.

To the extent patients participate in the drug selection process, they exercise heightened care because they are purchasing a product for health reasons. *See McNeil Nutritionals, LLC*, 511 F.3d at 365. Entresto is a prescription strength medication administered to patients with serious heart conditions after consultation with their doctors. Even assuming the patients are less sophisticated than their health care providers about these issues, the decision whether or not to embark on an Entresto treatment regime (or a generic equivalent) is undeniably one that involves great care and a substantial cost. Ardehali Decl. ¶¶ 27, 35–39; Shimer Decl. ¶ 20.[19]

[19] In *Kos Pharmaceuticals, Inc. v. Andrx Corp.*, 369 F.3d 700 (3d Cir. 2004), which Novartis cites, the court held that factor 3 was neutral, not that it favored the plaintiff. *See id.* at 717. Further, *Kos* is distinguishable because it did not involve medically equivalent medications, as here, instead two *different* medications for similar

Factor 5: MSN Had No Intent to Infringe. The unrebutted evidence demonstrates that the appearance of MSN's pills was driven by functional and regulatory considerations—not by any intent to create confusion. Nithiyanandam Decl. ¶¶ 13–14, 17. Novartis's attempt to equate intent to infringe with mere awareness of Entresto is wrong as a matter of law. This factor assesses *not* whether the defendant was aware of the plaintiff but whether the defendant "chose the mark to intentionally confuse customers." *Sabinsa Corp.*, 609 F.3d at 187. Indeed, it is not possible to create a generic version of a branded drug without being aware of the branded drug and that the vast majority of generics follow the physical attributes of the branded drug. *See* Clark Decl. ¶¶ 47–60. That is the whole purpose of the statutory framework behind generic drug development and FDA approval. This factor favors MSN.

Factor 6: There Is No Evidence of Actual Confusion. Novartis has known the MSN pills' appearance for over five years yet presents no consumer survey to try to show actual confusion. Novartis's choice not to "give[s] rise to the inference that the contents of the survey would be unfavorable." *Pharmacia Corp. v. Alcon Lab'ys, Inc.,* 201 F. Supp. 2d at 373 (D.N.J. 2002) ("[F]ailure to conduct any confusion

---

conditions, and there was evidence that mis-filled prescriptions might cause serious injury. *See id.* at 707. *Sabinsa Corp. v. Creative Compounds, LLC*, 609 F.3d 175, 186 (3d Cir. 2010), is even less apposite because it involved the market for ingredients for nutritional supplements, not prescription drugs.

survey weighs against [a] request for a preliminary injunction. . . . particularly when the trademark owner is financially able."). This factor also weighs in MSN's favor.

The Other Factors Are Irrelevant or Neutral. Because MSN has not yet begun using the accused trade dress in commerce, factor 4 is neutral. *Astrazeneca AB v. Dr. Reddy's Lab'ys, Inc*., 145 F. Supp. 3d 311, 317 (D. Del. 2015) (finding factor neutral where defendant's product had just launched).

Factors 7–10, which assess the parties' channels of trade, the targets of the parties' sales efforts, the products' function, and the likelihood that the defendant will expand into the plaintiff's market, are irrelevant due to the nature of the generic-branded drug relationship. In any event, Novartis's sweeping claims about these factors ignore some clear differences, for example, the fact that MSN (unlike Novartis) engages in no consumer-facing "sales efforts" and the fact that the parties' products will be sold at very different price points. Nithiyanandam Decl. ¶ 17; Chintapally Decl. ¶ 27.

II. NOVARTIS'S TRADEMARK CLAIM IS UNLIKELY TO SUCCEED.

Likewise, Novartis is not likely to succeed on the merits of its infringement claim based on MSN's use of the trademark NOVADOZ.

A. The Trademark Claim Is Barred in Its Entirety by Laches.

Novartis's delay in asserting this claim bars any relief whatsoever. Novartis, a sophisticated multi-billion-dollar company, has known of MSN's use of the

NOVADOZ trademark since at least August 2018, when MSN publicly announced its first three U.S. products under that mark. Chintapally Decl. ¶¶ 4, 11. Because Novartis did not sue until over six years later, a presumption of laches applies and Novartis bears the burden of proving that its delay was excusable and not prejudicial to Defendants. *See Kars 4 Kids Inc. v. America Can!*, 8 F.4th 209, 220–21 (3d Cir. 2021); *see also Kars 4 Kids Inc. v. America Can!*, 98 F.4th 436, 444–48 (3d Cir. 2024) (reversing district court for failure to place burden of proof on defendant).

Here, Novartis cannot overcome a presumption of laches. Novartis's trademark counsel contacted MSN about its application to register NOVADOZ in September 2019, but then did absolutely nothing until filing this lawsuit. Chintapally Decl. ¶ 25. And Novartis freely admits that it "has carefully monitored MSN's uses of NOVADOZ," Br. at 13 n.13, so it cannot claim ignorance of MSN's activities during that interval. Novartis knew, for example, that MSN launched at least two heart disease medications and that in 2021 it launched a generic that competed directly with a Novartis product. Srinivasan Decl. ¶ 10.

Novartis's attempt to argue that this lengthy delay can somehow be excused under a "progressive encroachment" theory is nonsense. *See* Br. at 33 n.21. First, Novartis has had actual knowledge of the physical appearance of MSN's accused pills for years. Chintapally Decl. ¶ 23. Second, Novartis has known about MSN's use of NOVADOZ as the U.S. marketing arm for dozens of MSN drugs and even

sent a patent-related cease-and-desist letter to *Novadoz* for its plans to market generic Entresto. Juang Decl. ¶ 12 & Ex. 8. Finally, MSN has not changed its use of NOVADOZ for more than six years and Novartis's theory of confusion—that this name invokes a combination of Novartis and Sandoz—is not based on any new facts.[20] Indeed, Novartis acquiesced to MSN's use of that name during the time period *when it actually owned Sandoz*. Now that Novartis has spun off Sandoz and assigned away any associated goodwill, its current attempt to resurrect that claim when it has not owned Sandoz for more than two years is even more far-fetched.

Further, Novartis's delay plainly prejudiced Defendants. Prejudice exists where the defendant "has continued to build a valuable business around its trademark during the time that the plaintiff delayed the exercise of its legal rights." *Kars 4 Kids*, 98 F.4th at 447. Here, while Novartis sat on its hands, MSN built an entire business around their NOVADOZ mark, which has come to embody MSN's reputation for quality and reliability in the eyes of its customers. Chintapally Decl. ¶¶ 33-34.

[20] The "progressive encroachment" doctrine does not apply where, as here, the purported encroachment simply reflects "a natural growth of [the defendant's] existing business." *Internet Specialties West, Inc. v. Milon-DiGiorgio Enters., Inc.*, 559 F.3d 985, 991 (9th Cir. 2009) (rejecting progressive encroachment argument based on defendant's shift from offering dial-up internet access to DSL access); *see also Kars 4 Kids*, 98 F.4th at 449 (finding no "progressive encroachment" justification for delay).

B. There Is No Likelihood of Confusion Between the Parties' Marks.

Regardless of laches, which again, is dispositive of Novartis's claim, analysis of the *Lapp* factors demonstrates that there is no likelihood of confusion:

Factor 1 (similarity of the marks): The parties' marks are dissimilar in terms of "appearance, sound, and meaning." *What a Smoke, LLC v. Duracell U.S. Operations, Inc.*, 2024 WL 1327976, at *7 (D.N.J. Mar. 27, 2024). The name NOVADOZ derives from "Nova," meaning a new bright star, and "doz," which sounds identical to and references the word "dose." Chintapally Decl. ¶ 5. The name is intended to convey an impression of newness and brightness while referencing the company's pharmaceutical products. *Id.* "Novartis," by contrast, is apparently based on the Latin term *novae artes*, meaning new skills.[21] *See EMSL Analytical, Inc. v. Testamerica Analytical Testing Corp.*, 2006 WL 892718, at *7 (D.N.J. Apr. 4, 2006) (acronyms dissimilar where meanings different). The marks also sound entirely different: the endings of the marks are dissimilar, and the letters that are common to both ("Nova") are pronounced differently ("NOH-vuh" versus "noh-VAR"). *See Engage Health Commc'ns, LLC v. Intellisphere, LLC*, 2018 WL 10339218, at *13 (D.N.J. Nov. 29, 2018) (PEER-SPECTIVES phonetically dissimilar to PEERS & PERSPECTIVES). The parties also use visually dissimilar branding. *See What a*

[21] Wikipedia, Novartis, https://en.wikipedia.org/wiki/Novartis (last visited Feb. 6, 2025).

Smoke, 2024 WL 1327976, at *7.[22]

Factor 2 (strength of Novartis's mark): Regardless of Novartis's vast marketing resources, its mark is weakened by the fact that there are over 300 registered marks beginning with "Nov" or "Nova" for pharmaceutical products and services alone, including "Novagen," "Novadur," "Novarel," *see* Carrero Decl. Ex. 4; *Citizens Fin. Grp., Inc. v. Citizens Nat. Bank of Evans City*, 383 F.3d 110, 123 (3d Cir. 2004) ("First, as a general rule, widespread use of even a distinctive mark may weaken the mark.").

Novartis cannot plausibly claim the exclusive right to use the prefix "Nova"—the only point of overlap between its mark and Defendants'—when third-party marks using the same prefix in the same industry are exceptionally common.

Factor 3 (consumer sophistication): This factor favors MSN or is neutral for the reasons explained above in connection with the trade dress claim.

Factors 4 and 6 (MSN's duration of use without actual confusion): "If a defendant's product has been sold for an appreciable period of time without evidence of actual confusion, one can infer that continued marketing will not lead to consumer

[22] The enormous number of third-party marks beginning with "Nova" refutes Novartis's unsupported claim that this is "dominant" portion of the parties' marks, as Novartis claims. *See* 3 McCarthy on Trademarks and Unfair Competition § 23:48 (5th ed.) ("If the common element of conflicting marks is a word that is 'weak' then this reduces the likelihood of confusion.").

confusion in the future." *Checkpoint Sys., Inc. v. Check Point Software Techs., Inc.*, 269 F.3d 270, 291 (3d Cir. 2001). Here, despite NOVADOZ coexisting in the market with NOVARTIS for close to seven years, Novartis offers no evidence whatsoever of actual confusion (and MSN is aware of none).

Factor 5 (intent): There is zero evidence that MSN intended to cause confusion with Novartis when adopting the mark NOVADOZ. Instead, the unrebutted evidence is that MSN built its mark by combining the prefix "Nova," signifying a bright star, and the suffix "doz," meaning "dose." Chintapally Decl. ¶ 5.

Remaining Factors and Summary: The remaining *Lapp* factors are irrelevant or neutral for the same reasons discussed above. With multiple factors favoring MSN and none favoring Novartis, Novartis cannot show any likelihood of confusion.

C. Novartis Cannot Salvage its Claim Based on Alleged Vestigial Confusion with a Former Corporate Affiliate

Novartis offers the implausible suggestion that consumers would associate MSN's generic heart medication with Entresto because Novartis used to own a third party named "Sandoz." See Br. at 12. This argument fails on multiple levels.

Novartis concedes, as it must, that it spun off its Sandoz division over two years ago and therefore it has not asserted any claim for trademark infringement of the Sandoz brand.[23] Compl. ¶¶ 7, 49; *see also Prime Hookah, Inc. v. Disc. Smoking*

[23] Novartis cites no case law supporting its right to complain about confusion with a trademark it has sold away. *See generally* Br.

Prods., Inc., 2019 WL 1650100, at *3 (D.N.J. Apr. 17, 2019) ("To have standing in an action for violation of trademark rights, a party must own the subject mark at the time the lawsuit is filed.").

As a result, Novartis' evidence of "use" of the Sandoz mark refers primarily to old photos of historical signage. *See* Decl. of Traci Dougherty ¶¶ 10–13. Indeed, Novartis acknowledges its only has a limited right to use Sandoz for some vague and undefined set of "preexisting materials." *Id.* ¶ 16.

Under these current market conditions, it is simply fanciful to suggest that any consumer would associate the names NOVARTIS and NOVADOZ merely because of the use of the common suffix "doz." This connection is even more attenuated as there are many third parties that use that suffix or its phonetic equivalent "dose" in connection with pharmaceutical companies and products. *See* Carrero Decl. Ex. 5.

III. NOVARTIS WILL NOT SUFFER IRREPERABLE HARM.

Irreparable harm is arguably the most important prerequisite for a preliminary injunction. *Marine Elec. Sys., Inc. v. MES Fin., LLC*, 644 F. Supp. 3d 84, 95 (D.N.J. 2022). "[T]he moving party must make a clear showing of immediate irreparable harm," and a "harm [that] will occur only in the indefinite future" is insufficient. *Macchione v. Coordinator Adm'r in Washington, D.C.*, 591 F. App'x 48, 49–50 (3d Cir. 2014) (quoting *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 96, 91 (3d Cir. 1992)). Further, "[t]he possibility that adequate compensatory or other corrective

relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm." *In re Revel AC, Inc.*, 802 F. 3d 558, 571 (3d Cir. 2015) (quoting *Sampson v. Murray*, 415 U.S. 61, 90 (1974)). "Where a plaintiff fails to adduce proof of actual or imminent harm which otherwise cannot be compensated by money damages, an injunction cannot issue." *Marine Elec. Sys.*, 644 F. Supp. 3d at 95.

A. Novartis's Delay Is Fatal to any Claim of Irreparable Harm

Novartis's multi-year delays in asserting its purported rights is fatal to any claim of irreparable injury. *See, e.g.*, *Ultimate Trading Corp. v. Daus*, 2007 WL 3025681, at *3 (D.N.J. Oct. 12, 2007) (denying preliminary injunction where plaintiff waited three months to sue and two more months to seek injunction); *Pharmacia Corp.*, 201 F. Supp. 2d at 385 (delay of over a year led to denial of preliminary injunction); *New Dana Perfumes Corp. v. The Disney Store, Inc.,* 131 F. Supp. 2d 616, 618 (M.D. Pa. 2001) (delays of two months in sending cease-and-desist letter and five months in seeking injunction "preclude a finding of irreparable harm"). The delays render any presumption of irreparable harm "inoperative." *Tough Traveler, Ltd. v. Outbound Products*, 60 F.3d 964, 968 (2d Cir. 1995); *Two Hands IP LLC v. Two Hands America, Inc.*, 563 F. Supp. 3d 290, 301 (S.D. N.Y. 2021) (statutory presumption of irreparable injury was rebutted because of failure to show a likelihood of confusion and because of plaintiff's three month delay.).

Contrary to its representations to the Court, Br. at 11 n.11, Novartis has known about Novadoz's plan to launch a generic version of Entresto and the appearance of those Novadoz's pills for *over four years*. Chintapally Decl. ¶¶ 21, 23. In June 2020, MSN produced its entire ANDA, including descriptions and photos of MSN's sacubitril/valsartan tablets, to Novartis's outside counsel. Juang Decl. ¶¶ 5-6 & Ex. A. And in January 2021, MSN sent Novartis physical samples of the pills, which Novartis evaluated and tested later that year.[24] Juang Decl. ¶ 9. Since that time, Novartis has been actively litigating against MSN in numerous courts and has been fully aware of the timing and circumstances of MSN's launch yet never complained about the appearance of the pills on grounds of trademark/trade dress infringement.

Likewise, Novartis has known for years about MSN's use of the NOVADOZ trademark on a wide variety of drugs, including heart medications and an equivalent of a Novartis branded drug. Srinavasan Decl. ¶ 7. And Novartis cannot feign ignorance of MSN's plans to use a NOVADOZ-branded label on its generic Entresto when it sent *Novadoz* a patent infringement cease-and-desist letter months ago without raising trademark concerns. *See* Juang Decl. ¶ 12. Novartis's delay bars its claim entirely under the doctrine of laches, but at a minimum it precludes a finding

[24] Even setting aside these productions, which Novartis did not disclose to this Court, Novartis admits that it has known about the Novadoz pills' appearance for nearly six months. Br. at 11 & n.11.

of irreparable harm.

B. Novartis's Speculative Theory of Reputational Harm Has Already Been Rejected.

Even setting aside its delay, Novartis entirely fails to show irreparable harm. Novartis primarily contends that it will suffer an irreparable loss of goodwill and control of reputation if consumers mistakenly attribute problems with MSN's product to Novartis's counterpart—without citing a single instance of actual confusion. But the D.C. District Court rejected this argument when it denied a preliminary injunction in Novartis's challenge to FDA's approval of MSN's ANDA, observing that "courts regularly reject as unduly speculative the argument that a brand-name manufacturer will lose general customer goodwill due to the deficiencies of a generic competitor." *Becerra*, 2024 WL 3823270, at *6. And Novartis's argument that "patients may not realize when their medication is being automatically substituted is not credible because . . . patient co-pays would presumably change upon prescriptions being swapped to a lower-priced generic." *Id.* at *7. This Court should follow the D.C. court's reasoned analysis.[25]

[25] Novartis's irreparable harm cases are inapposite. *Groupe SEC USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192 (3d Cir. 2014) involved household appliances, not prescription drugs. *AstraZeneca AB v. Camber Pharmaceuticals, Inc.*, 2015 WL 7307101 (D. Del. Nov. 19, 2015), involved over-the-counter drugs, not prescription drugs, and the court found that the defendant had *intended* to create the impression that its drug was *identical* to Nexium, not merely bioequivalent. *Id.* at *5.

C. Novartis's Alleged Economic Losses are Reparable

Last, Novartis's apparent claim that loss of market share is irreparable injury, *see* Robbins Decl. ¶¶ 18–27, is wrong as a matter of law. Such economic losses are fully compensable by a damages award. *See In re Revel AC, Inc.*, 802 F.3d at 571; *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 99 F. Supp. 3d 461, 501 (D.N.J. 2015) (noting that "loss of market share, lost sales, price erosion, and even employee layoffs" as a result of generic entering market are "reducible to a dollar value, and therefore not irreparable" harm). Indeed, the D.C. District Court reached this same conclusion in denying a preliminary injunction in Novartis's regulatory litigation. *See Becerra*, 2024 WL 3823270, at *4–5.

IV. THE BALANCE OF THE EQUITIES STRONGLY TIPS IN MSN'S FAVOR.

The extreme hardship MSN would suffer if faced with a preliminary injunction sharply tips the balance of equities in MSN's favor. This factor alone mandates denial of any preliminary injunction pending trial.

If MSN's launch is delayed, there is a significant risk that another generic would enter the market first—depriving MSN of its "first mover advantage" and ensuring MSN would likely never recover its research and development costs. Chintapally Decl. ¶ 30. Here, another company, Noratech, imminently expects FDA approval and will launch a competing Entresto generic, which will severely harm

MSN. *Id.* ¶ 32; Shimer Decl. ¶ 51.[26]

Notably, the District Court in Delaware denied a preliminary-injunction motion that Novartis filed against MSN for the same product at issue noting the balance of hardships tipped strongly in MSN's favor given the harm caused by any delay in bringing the product to market. *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, 2024 WL 3757086, at *5 (D. Del. Aug. 12, 2024) ("I am further convinced that MSN's potential harm from the loss of its first-mover advantage would outweigh the potential harm to Novartis."); *see also Otsuka Pharm. Co.*, 99 F. Supp. 3d at 506 (noting that "the hardship on a preliminarily enjoined generic which has taken affirmative steps to enter the market can be devastating").

Novartis's flippant suggestion that MSN can simply release its generic in another shape, *see* Br. at 23, is flat wrong. As Novartis is fully aware, the shape and size of a pill directly affect dissolution and absorption in the body. MSN would have to conduct extensive testing before launching reconfigured pills, which would take two years, if not longer. Chintapally Decl. ¶¶ 35–36.

[26]Moreover, MSN has been placed in the untenable position of being in a "go/no go" posture around the launch of its product for months, causing significant harm to its efforts to engage in a commercially reasonable launch of the product. Any further unexpected delay caused by Novartis's surprise motion for emergency relief in this case—even just a few weeks—would irreparably harm MSN's reputation for reliability and impede its ability to negotiate with potential buyers. Chintapally Decl. ¶ 30; Shimer Decl. ¶¶ 58–63.

Nor can Novartis discount this severe and irreparable harm by claiming it is self-inflicted. *See* Br. at 40.[27] MSN developed its generic Entresto product in good-faith compliance with FDA guidelines for generic drugs, including the guideline that they should be similar in appearance to their branded counterparts. It is absurd for Novartis to argue that MSN brought harm on itself simply by complying with regulatory requirements.

V. AN INJUNCTION IS AGAINST THE PUBLIC INTEREST.

Patients have an interest in the availability of affordable alternatives to brand-name drugs. *See, e.g.*, *Otsuka Pharm. Co.*, 99 F. Supp. 3d at 507 (finding public interest in increased competition in marketplace for generic pharmaceuticals supported denial of injunction); *Genentech, Inc. v. Immunex Rhode Island Corp.*, 395 F. Supp. 3d 357, 366 n.6 (D. Del. 2019), *aff'd*, 964 F.3d 1109 (Fed. Cir. 2020) (denying preliminary injunction where there was "critical public interest in affordable access to [lifesaving] drugs"); Clark Decl. ¶¶ 31–32; Shimer Decl. ¶¶ 17–23. Bringing MSN's generic to market would mean doctors have greater flexibility to prescribe a highly effective, life-saving medicine without worrying about whether

[27] The only case Novartis cites in support of this argument could not be factually more different. In that case, the defendant, the plaintiff's former distributor, plotted to "take [the plaintiff's] mark," "used [a] double agent to execute a scheme to bring a competing [product] to market under the [plaintiff's] mark, and all the while deceived [the plaintiff]—a longstanding and amicable business partner—as to the state of their relationship and FIUS's intentions." *Family Inada Co. v. FIUS Distributors LLC*, 2019 WL 5295178, at *8 (D. Del. Oct. 18, 2019).

patients could afford it. Ardehali Decl. ¶¶ 35–37; Shimer Decl. ¶ 29; *see also Warner Lambert Co. v. McCrory's Corp.*, 718 F. Supp. 389, 399 (D.N.J. 1989) (holding that the public interest is best served by allowing defendant to sell its lower priced product pending outcome of the action).

If it is preliminarily enjoined, MSN has no ability to quickly reconfigure its product and relaunch it with a different appearance. Shimer Decl. ¶ 50. Thus, an injunction would deprive patients of an affordable alternative to a life-saving heart medication for months or years while this case is litigated. *Id.* As another court held just last month in denying a TRO in yet another lawsuit by Novartis against MSN involving Entresto, "[w]here a generic manufacturer met all relevant safety and approval standards, there is a clear public interest in receiving generic competition to brand-name drugs as soon as possible." Juang Decl. Ex. 11 at 12:20–25.

Novartis's public interest arguments do not hold water. First, Novartis's fearmongering about putative public safety concerns arising from the omission of certain dosing information on MSN's product label is entirely unfounded. FDA and the D.C. District Court have already rejected Novartis's attack on MSN's labeling. *See Becerra*, 2024 WL 4492072, at *7. And Novartis's hypothesized scenario where a doctor might inadvertently refer to the wrong prescribing information and start a patient on the wrong dose is not only entirely speculative but also highly unlikely. *See* Ardehali Decl. ¶¶ 27–34; Clark Decl. ¶ 61; *see also Reedco, Inc. v. Hofzfman-*

La Roche, Inc., 667 F. Supp. 1072, 1080 (D.N.J. 1987) (citation omitted) ("[T]he unintended use of one drug instead of another, similarly named drug, could only have resulted [from] the spectacular incompetence of a physician or nurse.").

Novartis's appeal to patient autonomy is even less persuasive. Again, the D.C. District Court has held that it is "not credible" for Novartis to speculate that patients will not realize when a generic drug has been substituted for Entresto, because "patient co-pays would presumably change upon prescriptions being swapped to a lower-priced generic." *Becerra*, 2024 WL 3823270, at *7. It is also not plausible that any significant group of patients will continue to insist on brand-name Entresto after a generic is available, because health insurance plans generally mandate generic substitution. *See* Clark Decl. ¶¶ 21–22. Finally, any such group's interest in preferring branded Entresto over a bioequivalent generic alternative is plainly outweighed by the public interest in making MSN's safe, effective, and affordable product available to patients.

CONCLUSION

For the foregoing reasons, the Court should deny Novartis's motion.

Dated: February 6, 2025

Respectfully submitted,

/s/ Rebekah Conroy
Rebekah Conroy
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
(973) 400-4181
rconroy@stoneconroy.com

Ron Daignault (*pro hac vice application forthcoming*)
Richard Juang (*pro hac vice application forthcoming*)
DAIGNAULT IYER LLP
8229 Boone Boulevard, Suite 450
Vienna, VA 22182
(917) 838-9795

Gianni P. Servodidio (*pro hac vice* application forthcoming)
Jenner & Block LLP
1155 Avenue of the Americas
New York, NY 10036
Tel: (212) 891-1600
Fax: (212) 891-1699
gservodidio@jenner.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of February, 2025, I caused a copy of the foregoing to be served upon all counsel of record via ECF notification.

/s/ Rebekah Conroy
Rebekah Conroy